

REMARKS

The specification has been amended to correct minor errors and better describe the invention. No new matter has been introduced.

Applicants respectfully urge that the claims of the present application define patentable subject matter and should be passed to allowance. Such allowance is respectfully solicited.

If the Examiner believes that a telephone call would help advance prosecution of the present invention, the Examiner is kindly invited to call the undersigned attorney, mR. Khaled Shami, at (650) 622-2332.

Respectfully submitted,

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Attachment to Preliminary Amendment

Marked-up Copy

Page 8, Paragraph beginning at Line 1

Test strip 1 is provided with an alignment mechanism which may have features 5 and 10 designed to mate [wit] with features 20 and 25 on optics shield 15. These are designed to issue positive alignment of the test strip to the optics. It is contemplated that other configurations meeting the intent of the invention are within the scope of this invention.

Page 5, Paragraph beginning at Line 16

The system must also be able to accurately dock the test strip with the optics system including led, detector, lenses or light pipes. To achieve this a centerline alignment, or fixturing, system which minimizes rotation of the test strip carrier is required. The need to accurately describe the test strip performance with respect to the analyte concentration also helps accuracy.

Page 11, Paragraph beginning at Line 3

The test strip 1 is comprised of a test pad 12 situated in a test pad holder 13. This holder mounts to strip fluid delivery system 14 and [parts 13 and 14] parts 5 and 10 provides a means for accurately positioning the test pad 12 with respect to the LED 50, and the

detector 60 in addition to providing a means for blocking ambient light from effecting the analysis. The test pad 12 is impregnated with the appropriate chemistry to permit a colormetric analysis of the analyte being tested and may therefore provide a stable absorbent substrate.

Page 11, Paragraph beginning at Line 10

The test strip of this invention provides a support for the test pad. The strip positively seats on the testing instrument, assuring proper alignment through center line fixturing. It also seals the optics area from ambient light and blood contamination. Thus, it provides all of the functionality of a test strip and test strip holder of a conventional reflectance system. The test strip provides additional benefits in being removed after each test, facilitating easy access to the optics area for cleaning if required. With this combination part, the overall cost of the system is further reduced. When inserted into the detection device [180] 151, the test strip 1 contacts complete a circuit which turns the device on. The device is turned off upon removal of the test strip. This eliminates a need for a separate on/off circuit or for patient action to turn the testing instrument on or off.

Page 13, Paragraph beginning at Line 9

FIG. 5A is a block diagram showing the processing operation of the invention. Testing instrument 151 comprises a microprocessor 80 which controls the operation of the testing instrument 151. The testing instrument 151 is activated by a switching mechanism which

results can be downloaded. One possibility in accordance with the invention is a modem link with a remote processing unit, using, e.g., telephone lines. The information may also be downloaded for storage at an internet location or electronic bulletin board for subsequent retrieval and processing or review by medical professionals. See application Serial No. 09/190,301 filed November 13, 1998, incorporated herein by reference in its entirety.

Page 15, Paragraph beginning at Line 1

The color formed after applying the bodily fluid to the reagent test pad is proportional to the amount of analyte in the applied sample 250. The testing instrument 151, via sensor 60, ASIC [190] 185 and microprocessor 80, measures the change in reflectance due to the development of the specific color generated by the reagent on the test strip 1. This is either used as the input to a function which relates reflectance to analyte level or to a table which correlates reflectance value to analyte level. The function or the table must be stored within the system for it to produce and display, on display 200, a reading of the analyte level in the sample [16] 250. While most meters in use today employ functions to convert reflectance readings to analyte concentration, this approach requires that the function be stable and well understood. The use of a look up table permits the storage of specific values for reflectance and their corresponding analyte levels. The testing instrument uses this table and interpolates between the table values to give relatively accurate readings. This is achievable in a system such as that described by this invention as the table can quickly be generated for each reagent lot produced.

Page 15, Paragraph beginning at Line 27

In the preferred embodiment, calibration is based on the response produced by a specific lot of test strips. In this manner, there is no need to presort and test the LED 50, significantly reducing the cost of the sensor 60. The LED 50 and photodetector 60 formed from raw die elements and are placed by automated placement equipment with respect to predetermined targets on the printed circuit board. In addition, this calibration step during manufacture allows the device to compensate for a wide area of variables normally found in reflectance systems. The specific calibration data for the test strips 1 shipped with the testing instrument can be stored in the unit's read only memory (not shown). Alternatively, a master strip can be provided for setting the calibration information for that lot of strips and the master strip can be distributed therewith. A counter may be provided to limit the testing instrument [80] 151 to performing only a specific number of tests which correlates to the quantity of test strips 1 shipped with the device. Other limitations can be built-in, such as expiration date information pertaining to the specific lot of test strips 1, with this information being contained in the measuring instrument's ROM or in the calibration chip 90 or in the master strip.



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